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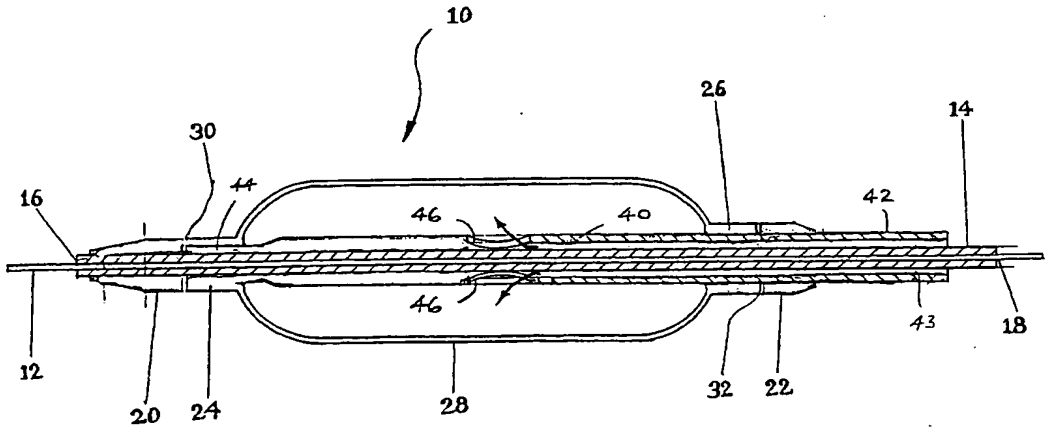
(54) Title: ROTATING STENT DELIVERY SYSTEM FOR SIDE BRANCH ACCESS AND PROTECTION AND METHOD OF USING SAME.



(57) Abstract: A catheter assembly and method of use comprises advancing a catheter having a rotatably mounted balloon (28,28') relative to the primary guide wire (12,12') to a vessel bifurcation along first and second guide wires (62).

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TITLE

Rotating Stent Delivery System for Side Branch Access and Protection and Method of Using Same

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority from US provisional application 60/314,467, filed August 23, 2001 the entire contents of which are incorporated herein by reference.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

Not Applicable

BACKGROUND OF THE INVENTION

Field of the Invention

At least one embodiment of the present invention is directed to the field of stents and stent delivery systems used to treat stenoses, and more particularly to stenoses at a bifurcation of a passage.

Description of the Related Art

Stent systems are widely used in the treatment of stenoses. Intravascular stents are used in coronary, renal, and carotid arteries, for example, to maintain an open passage through the artery. In patients whose coronary heart disease consists of focal lesions, stents have proven effective. For example, where only a single coronary artery is clogged or where there are short blockages in more than a single artery, stents have been used with a great amount of success. An intravascular stent may be positioned in a clogged artery by a catheter and is often set in place by inflating a balloon upon which the stent is mounted. This expands the diameter of the stent and opens the previously clogged artery. The balloon is then deflated and removed from the patient while the stent retains an open passage through the artery.

It is recognized, however, that a stent can be deployed in manners other than inflating and deflating a balloon. For example, self-expanding stents have been

developed in which a cover is removed from over a stent, thereby allowing the stent to deploy or spring into place. It is also contemplated that other deployment mechanisms or means may be used or developed to advantageously deliver and deploy a stent in position.

Nevertheless, a need still exists for properly delivering and locating a stent at a bifurcation. Although efforts have been made to use a stent at bifurcations, these sites have previously been inadequately treated by a stent. For example, U.S. Patent No. 5,749,825 is representative of a catheter system that treats stenoses at an arterial bifurcation. The disclosure of 5,749,825 is hereby incorporated by reference.

A stent having different diameters has been proposed to allow placement in both a main passage, such as an artery, and a side branch passage, such as a continuation branch artery. Additionally, these stents generally have a circular opening which allows for unimpeded blood flow into the side branch artery. However, problems are still encountered in orienting the stent relative to the side branch at the bifurcation of the main and branch passages.

Many current devices rely on either passive torque (e.g., pushing the stent forward and allowing the stent that is fixed on the guide wire/balloon to passively rotate itself into place) or creating torque from outside of the patient to properly orient the stent delivery system in the passage. These devices and methods of achieving proper angular orientation have not been shown to be effective in properly placing and positioning the stent. As will be appreciated and understood by those skilled in the art, improper placement of the stent with respect to its rotational or circumferential orientation, or its longitudinal placement, could lead to obstruction of the side branch passage. It is important to properly position or center an opening formed in the bifurcated stent with the side branch passage to maximize flow therethrough.

Thus, a need exists for effectively treating stenosed passage bifurcations. This need includes more precise and exact longitudinal placement and rotational/ circumferential orientation of the stent.

Commercially available devices do not maintain side branch access at the time of stent deployment. This results in the potential for plaque shift and occlusion of

the side branch passage.

It would also be advantageous if stents could be placed across the side branch while wire position is maintained thereby helping to protect and secure further access to the side branch.

All US patents and applications and all other published documents mentioned anywhere in this application are incorporated herein by reference in their entirety.

Without limiting the scope of the invention a brief summary of some of the claimed embodiments of the invention is set forth below. Additional details of the summarized embodiments of the invention and/or additional embodiments of the invention may be found in the Detailed Description of the Invention below.

A brief abstract of the technical disclosure in the specification is provided as well only for the purposes of complying with 37 C.F.R. 1.72. The abstract is not intended to be used for interpreting the scope of the claims.

BRIEF SUMMARY OF THE INVENTION

Some embodiments of the present invention include a freely rotating deployment system for a stent assembly maintaining side branch access and protection.

The present invention contemplates a new and improved apparatus and method that improves the orientation of a stent by providing a more exact placement of the stent relative to the side branch passage. This, in turn, leads to better protection of the side branch passage. The present invention has the potential for improvement in trackability of the stent delivery system.

At least one embodiment of the invention includes a freely rotatable catheter balloon surrounding a main hollow member or hypotube. The stent surrounds both the catheter balloon and the main hypotube. A side branch hollow member or side branch hypotube is attached to the catheter balloon and lies underneath the stent. A distal end of the side branch hypotube exits the stent at a desired longitudinal position while a proximal end of the side branch hypotube extends beyond the proximal end of the stent. At the distal exit point, the stent

includes an opening that, after deployment of the stent, allows for blood flow through the ostium of the side branch artery.

The balloon is connected to the stent delivery system. In some embodiments, the balloon is attached both distally and proximally to rotate freely about the main hypotube. The rotating members rotate about the main hypotube and are limited longitudinally by first and second fixed members non-rotatably secured to the *main* hypotube. The *balloon* stent assembly rotates freely about the axis defined by the main hypotube and any radial movement is limited by the main hypotube. This construction allows the side branch guide wire to direct the stent assembly to rotate freely and passively to the proper circumferential orientation. Upon inflating the balloon, the fixed and rotated members secure the circumferential orientation of the stent delivery system. Thus, the side branch guide wire properly orients the stent delivery system in its correct position relative to the side branch.

A primary feature of some embodiments is that at the time of positioning the stent, the stent will be properly oriented relative to the side branch, i.e., a stent delivery system and method that correctly positions the stent in a bifurcated passage.

Another advantageous feature is side branch protection with the guide wire during stent deployment.

Another benefit of this invention resides in proper alignment of the stent delivery system in a bifurcated passage to achieve correct circumferential orientation relative to a side branch passage, and securing the desired orientation.

Yet another benefit of this invention is the ability to properly place the stent delivery system longitudinally relative to the side branch.

A further advantage of the system is that tangled wires pose less of a problem.

These and other embodiments which characterize the invention are pointed out with particularity in the claims annexed hereto and forming a part hereof. However, for a better understanding of the invention, its advantages and objectives obtained by its use, reference should be made to the drawings which form a further part hereof and the accompanying descriptive matter, in which there is illustrated and described a embodiments of the invention.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

A detailed description of the invention is hereafter described with specific reference being made to the drawings.

FIG. 1 is a cross-sectional side view of a rotating stent delivery catheter assembly for stenting an arterial bifurcation in its pre-deployment configuration, with the catheter balloon shown inflated.

FIG. 2 is a perspective view of the stent delivery assembly of FIG. 1 shown with a stent disposed about the balloon.

FIG. 3 is a perspective view of the stent delivery catheter assembly of FIG. 1 as it would appear in the collapsed state prior to having a stent mounted on the balloon.

FIG. 4 is a perspective view of a stent delivery system with the balloon in an inflated state and the side branch hypotube in an open condition.

FIG. 5 is an enlarged view of the distal exit point of the side branch hypotube and the opening of the rotating stent delivery catheter assembly of FIG. 2.

FIG. 6 is a perspective view of a proximal shaft of an alternate stent delivery catheter assembly having only one rotating joint that is self sealing when pressure is applied or withdrawn.

FIG. 7 is an enlarged side view of a distal end of the rotating balloon assembly associated with FIG. 6.

FIG. 8 is an enlarged side view of the combined components of FIG. 6 and 7, specifically portions of the distal end of the proximal fixed shaft in FIG. 6 combined with the proximal end of the freely rotatable distal portion in FIG. 7 creating a rotating stent delivery catheter assembly with a single rotating joint that is self sealing.

FIG. 9 is an enlarged side elevational view of FIG. 6 and 7 showing the combined of components of FIGS. 6-8 in their entirety.

DETAILED DESCRIPTION OF THE INVENTION

While this invention may be embodied in many different forms, there are described in detail herein specific preferred embodiments of the invention. This description is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

For the purposes of this disclosure, like reference numerals in the figures shall refer to like features unless otherwise indicated.

Referring now to the drawings wherein the showings are for the purposes of illustrating the preferred embodiments of the invention only and not for purposes of limiting same, FIG. 1 shows a stent delivery system or assembly 10. Assembly 10 includes a first guide member, or main guide wire 12 that extends axially through a first hollow or tubular member 14. The first hollow member 14 will also be identified as a main hypotube, although it will be appreciated that the particular shape or configuration of this component may change from that illustrated in the drawings. The main guide wire 12 is used as the delivery guide of the stent catheter assembly 10 to a stenosed region of a passage such as an artery (not shown). The main hypotube 14 is preferably a hollow cylinder with openings on both its distal and proximal ends, respectively end 16 and end 18, which allows for passage of the main guide wire 12 therethrough. A first fixed member, or distal fixed body 20 and a second fixed member, or proximal fixed body 22 are non-rotatably secured to distal end 16 and proximal end 18 of the main hypotube 14. Although described as separate elements, it will be understood that the fixed bodies 20 and 22 and the main hypotube 14 can be separate components that are secured together or an integrally formed assembly if desired for ease of manufacture or assembly. The fixed bodies 20 and 22 are preferably tapered from smaller diameter, axially outer ends to larger diameter, intermediate ends for reasons that will become more apparent below.

A first rotating member or distal rotating member 24 and a second rotating member or proximal rotating member 26 are axially spaced apart and located between the distal fixed body 20 and proximal fixed body 22. The rotating members 24 and 26 are preferably of the same general diameter throughout their length and rotate freely about the axis of the main hypotube 14.

Sealed to the proximal and distal rotating members 24 and 26 are opposite ends of a catheter balloon 28. A distal end 30 of the catheter balloon is sealingly joined to (or

integrally formed with) the distal rotating member 24 while a proximal end 32 of the catheter balloon is sealingly joined to (or integrally formed with) the proximal rotating member 26. Thus, the balloon is free to rotate relative to the main hypotube, a feature that provides advantages and benefits over known stent assemblies. It is also contemplated that the rotating members 24 and 26 can be formed of sealing or elastomeric material (or incorporate a separate seal member) so that slight axial movement of the balloon 28 and of the rotating members 24 and 26 engages and seals against the fixed bodies 20 and 22 upon inflation of the balloon 28. The balloon 28 and the rotating members 24 and 26 can hold high pressure and seal at the ends. It will be appreciated that the rotating members 24 and 26 are preferably constructed to maintain a cylindrical configuration under pressure so that the balloon 28 is free to rotate relative to the main hypotube 14 when pressurized.

In some embodiments the stent delivery catheter system further includes an outer hollow/tubular member or outer hypotube 40 received over the main hypotube 14. The outer hypotube 40 is radially spaced from the main hypotube 14 at a first or proximal end 42 to define an annular space 43 through which fluid from an external source (not shown) is introduced to inflate the balloon. In at least one embodiment, a second or distal end 44 of the outer hypotube 40 is sealed to the main hypotube 14 so that fluid cannot escape therefrom. Alternatively, the distal end of the outer hypotube extends only partially into the balloon 28. In addition, one or more openings, or contrast ports, 46 are provided in the outer hypotube 40 at a location within the balloon 28 so that the fluid can enter the cavity defined between the balloon 28 and the outer hypotube 40 as illustrated by the directional arrows in FIG. 1. Alternatively, the opening 46 may define the distal end of the outer hypotube 40. In at least one embodiment, the balloon 28 is fully inflated at the proximal end 42 and then begins to inflate at the distal end 44. The outer hypotube 40 may be advantageously and integrally formed with the first and second fixed members 20 and 22 for ease of manufacture, although it will be appreciated that these may be separate members without departing from the scope and intent of the invention.

A conventional or specially designed medical device, such as a stent 50, encloses a portion of the catheter balloon 28, such as is shown in FIG. 2. The stent 50 is typically a metal sleeve of mesh construction that is advanced into the stenosis riding on the balloon 28 of the catheter assembly 10. Once properly positioned, the balloon 28 is inflated with an inflation

fluid, such as saline and contrast, through the passage 43 between the main hypotube 14 and the outer hypotube 40, which expands the balloon 28 and expands or radially opens the stent 50 to compress an atheroma that is narrowing the passage wall. Although the balloon 28 is subsequently deflated for removal from the patient with the catheter assembly 10, the stent 50 remains in its expanded state allowing increased flow through the previously closed/blocked (stenosed or narrowed) region. Alternatively, a self-expanding stent not requiring a balloon for delivery or deployment can be used without departing from the scope and intent of the present invention.

A second or branch tubular member 60, also referred to as a side branch hypotube, is provided between the catheter balloon 28 and the stent 50. As evident in FIG. 2, the side branch hypotube 60 carries or receives a side branch guide wire 62. The side branch hypotube 60 extends from the proximal end of the stent 50 between the stent and balloon and exits the stent at an intermediate longitudinal position through an opening 64. The opening 64 provides for both the exit of the side branch hypotube 60, as well as the unobstructed passage of blood flow into the side branch passage once the stent has been deployed. It should be understood, however, that the side branch hypotube opening 64 could be placed at any convenient position along the stent.

An enlarged view of the side branch hypotube opening 64 in the stent 50 is shown in FIG. 5. The side branch hypotube 60 exits from underneath the proximal end of the stent. Upon deployment of the stent 50, the side branch hypotube opening 64 allows for unobstructed blood flow to the ostium of the side branch passage. As will also be appreciated, the side branch hypotube 60 is fixed or secured to the exterior of the balloon. Thus, the side branch hypotube 60, balloon 28, and rotating members freely rotate as a unit relative to the main hypotube 14 for accurate, passive positioning with the side guide wire and thus accurate positioning of the stent 50 relative to a saddle point of the bifurcated passage. With continued reference to FIG. 2, the catheter balloon 28 is inflated, the stent 50 is deployed, and the rotating members 24 and 26 are interlocked with the fixed members 20 and 22 to stop the rotating action of the stent delivery system and create a pressure tight system.

The side branch hypotube 60 may also be slit 66 along its longitudinal length to facilitate removal of the side guide wire 62 as is shown in FIGs. 3 and 4. The side branch

hypotube 60 is secured to the balloon 28 along its length at a circumferential location opposite the longitudinal slit, i.e., diametrically opposite the slit 66. The natural elasticity of the side branch hypotube 60 is utilized so that when the balloon 28 is inflated, such as is shown, the side branch hypotube 60 is substantially cylindrical in shape to enclose the portion of the side guide wire 62 therein such as is shown in FIG. 2. When the balloon is inflated, it exerts a tensile force on the side branch hypotube 60 that opens the hypotube 60 along its length, such as in the manner shown in FIG. 4. As a result the side guide wire 62 is released through the slit 66. When the balloon 28 is deflated, such as is shown in FIG. 3, the side branch hypotube 60 again adopts a cylindrical conformation whereby the remainder of the stent delivery system (balloon and catheter) can be easily removed.

The split side branch hypotube 60 offers another desirable feature. The split hypotube 60 allows for immediate placement of a second balloon into the side branch for simultaneous "kissing" balloon inflation. In other words, first and second balloons are simultaneously located in the main and side branch passages such that their proximal ends abut and their distal ends are placed in each respective branch. This is to be contrasted with use of an unsplit or solid side branch hypotube which would require removal of the first balloon prior to insertion of a balloon in the side branch.

An alternative rotating stent delivery system is illustrated in FIGs. 6-9. For purposes of brevity, like components will be referenced by like numerals with a primed suffix (') and new elements will be identified by new numerals.

A proximal shaft is generally well known in the art and may take numerous forms; however, the proximal shaft 70 shown in FIGs. 6-9 preferably includes a bushing 72 at a distal end and a seal 74 comprised of a soft material. The seal 74 is connected to the proximal shaft 70 and, as shown, tapers to a smaller diameter and envelops the main hypotube 14', as is shown in FIGs. 8 and 9. Within lumen 76 of the proximal shaft 70, the bushing 72 abuts against an interior distal end of the proximal shaft.

With reference now to FIG. 7, a distal rotating portion of proximal shaft 70 is shown. A separate hypotube 14' includes a proximal end with a first bushing 80 and a second bushing 82 axially spaced therefrom along the separate hypotube 14'. A second seal 84 comprised of a soft material, is connected to the first bushing 80 at the proximal end of the

separate hypotube 14'. The annular second seal 84 protrudes substantially parallel along the longitudinal axis of the main hypotube and extends axially beyond an opening 86 for the main branch guide wire (not shown). Additionally, a third annular seal 88 is shown connected to the first bushing 80. The third seal 88 has a smaller diameter and lies axially and radially inward of the second seal 84. The third seal 88 is also secured to the first bushing 80 of the separate hypotube 14' and tapers radially inward as it extends longitudinally in a direction away from the separate hypotube 14', to envelope the main guide wire 12'.

The integration of the proximal end of the separate hypotube 14' and the distal end of the proximal shaft 70 is shown in FIG. 8. Particularly, the first and second bushings 80, 82 of the hypotube 14' are of a diameter that allows them to fit under or within the particular components of the proximal shaft 70. Specifically, the second bushing 82 of the hypotube 14' is distal to the proximal shaft bushing 72 and is enveloped by the first soft seal 74 of the proximal shaft 70. The first bushing 80 of the hypotube 14' is adjacent to the bushing 72 of the proximal shaft and is enveloped by the proximal shaft 70.

With continued reference to FIG. 8, the integrated hypotube 14' and proximal shaft 70 are shown in a freely rotatable position. In this mode, the hypotube 14' rotates freely while the proximal shaft 70 remains fixed. Positive pressure allows the seals 82 and 88 extending from the first bushing 80 of the hypotube 14', to contact the proximal fixed shaft 70 and main guide wire 12' hence sealing the balloon delivery system 10' allowing for all positive pressure to be transferred to the balloon 28'. This provides for expansion of the balloon 28' and deployment of a stent such as previously described. Alternatively, as is shown in FIG. 9 negative pressure applied within the shaft 70 will create contact between the separate hypotube and the seal 74 of the proximal shaft 70. Also, contact will be created at the distal end of the separate hypotube between the soft material and the wire 12' creating a seal there as well. These seals allow for all negative pressure to be transmitted to the balloon allowing for collapse and then removal of the balloon.

Thus, it is apparent that a truly unique feature of the invention is a freely rotating stent assembly that provides a more exact placement of the stent relative to the side branch passage.

The invention has been described with reference to the preferred

embodiments. Obviously, modifications and alterations will occur to others upon a reading and understanding of this specification. For example, the illustrated embodiments use a balloon to expand the stent although, as briefly noted above, a self expanding or self deploying stent can be used without departing from the features of the present invention. Likewise, using a fixed wire on the distal end of the apparatus is also recognized as being consistent with the features of the present invention. Moreover, the preferred embodiments describe a side branch hypotube, either split or unsplit, that is associated with the side branch guide wire. It will be further appreciated that the side branch guide wire could be carried and/or released in a variety of other ways. The invention is intended to include all such modifications and alterations thereof.

The above disclosure is intended to be illustrative and not exhaustive. This description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the claims where the term "comprising" means "including, but not limited to". Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims.

Further, the particular features presented in the dependent claims can be combined with each other in other manners within the scope of the invention such that the invention should be recognized as also specifically directed to other embodiments having any other possible combination of the features of the dependent claims. For instance, for purposes of claim publication, any dependent claim which follows should be taken as alternatively written in a multiple dependent form from all prior claims which possess all antecedents referenced in such dependent claim if such multiple dependent format is an accepted format within the jurisdiction (e.g. each claim depending directly from claim 1 should be alternatively taken as depending from all previous claims). In jurisdictions where multiple dependent claim formats are restricted, the following dependent claims should each be also taken as alternatively written in each singly dependent claim format which creates a dependency from a prior antecedent-possessing claim other than the specific claim listed in such dependent claim below.

This completes the description of the preferred and alternate embodiments of the invention. Those skilled in the art may recognize other equivalents to the specific embodiment described herein which equivalents are intended to be encompassed by the claims attached hereto.

CLAIMS:

1. A catheter assembly comprising:

an elongate guide member, the elongate guide member extending from a proximal end to a distal end of the catheter assembly;

a tubular member disposed about a portion of the elongate guide member, the tubular member rotatable about the elongate guide member;

an expandable medical balloon having a proximal end and a distal end, the medical balloon disposed about at least a portion of the tubular member, the proximal end and the distal end of the medical balloon fixedly engaged to the tubular member; and

a proximal shaft member, the proximal shaft member disposed about a portion of the elongate guide member, the proximal shaft member having a distal end region, the distal end region being disposed about a proximal end region of the tubular member, the tubular member passively rotatable relative to the proximal shaft.

2. The catheter assembly of claim 1 wherein the tubular member defines an inflation port, the inflation port constructed and arranged to transmit an inflation media to and from the medical balloon from and to the proximal end of the catheter assembly.

3. The catheter assembly of claim 1 wherein the distal end region of the proximal shaft member is sealingly engaged to the proximal end region of the tubular member.

4. The catheter assembly of claim 1 wherein the proximal end region of the tubular member comprises a first bushing and the distal end region of the proximal shaft member comprises a second bushing, the first bushing engaged to the second bushing to form a fluid tight seal between the proximal end region of the tubular member and the distal end region of the proximal shaft member.

5. The catheter assembly of claim 4 wherein the proximal end region of the tubular member further comprises a third bushing, the second bushing positioned between the first bushing and the second bushing.

6. The catheter assembly of claim 3 further comprising a first annular seal, the first annular seal extending from the distal end region of the proximal shaft member to the proximal end region of the tubular member.

7. The catheter assembly of claim 6 wherein the first annular seal tapers from a first end engaged to the distal end region of the proximal shaft member to a narrower second end engaged to the tubular member.

8. The catheter assembly of claim 7 further comprising a second annular seal, the second annular seal extending from the distal end region of the proximal shaft member to the proximal end region of the tubular member, the second annular seal being positioned proximal to the first annular seal.

9. The catheter assembly of claim 8 further comprising a third annular seal, the third annular seal extending from the proximal end region of the tubular member to the elongate guide member.

10. The catheter assembly of claim 9 wherein the third annular seal tapers from a first end engaged to the proximal end region of the tubular member to a narrower second end engaged to the elongate guide member.

11. The catheter assembly of claim 1 wherein a proximal end region of the tubular member is sealingly engaged to the elongate guide member.

12. The catheter assembly of claim 11 further comprising a third annular seal, the third annular seal extending from the proximal end region of the tubular member to the elongate guide member.

13. The catheter assembly of claim 1 further comprising an expandable and implantable medical device, the expandable and implantable medical device being removably disposed about at least a portion of the medical balloon.

14. A catheter assembly comprising:

an elongate guide member, the elongate guide member extending from a proximal end to a distal end of the catheter assembly;

a tubular member disposed about a portion the elongate guide member, the tubular member rotatable about the elongate guide member;

a medical balloon having a proximal end and a distal end, the medical balloon disposed about at least a portion of the tubular member, the proximal end and the distal end of the medical balloon fixedly engaged to the tubular member; and

a proximal shaft member, the proximal shaft member disposed about a portion of the elongate guide member, the proximal shaft member having a distal end region, the distal end region of the proximal shaft member being disposed about a proximal end region of the tubular member, the distal end region of the proximal shaft member and the proximal end region of the tubular member forming a fluid tight seal therebetween, the tubular member being passively rotatable relative to the proximal shaft member.

15. The catheter assembly of claim 14 further comprising a stent, the stent being disposed about at least a portion of the medical balloon, the stent being expanded from a reduced state to an expanded state when the medical balloon is expanded.

16. A catheter assembly comprising:

an elongate guide member, the elongate guide member extending from a proximal end to a distal end of the catheter assembly;

an inner tubular member, the inner tubular member disposed about a portion of the elongate guide member;

an outer tubular member, the outer tubular member disposed about at least a portion of the inner tubular member;

a proximal rotatable member and a distal rotatable member, the proximal rotatable member being disposed about a proximal portion of the outer tubular member, the distal rotatable member being disposed about at least one of the distal portion of the inner tubular member and the distal portion of the outer tubular member, the proximal rotatable member forming a slidable and rotatable fluid seal with the proximal portion of the outer tubular member and the distal rotating member forming a slidable and rotatable fluid seal with the at least one of the distal portion of the inner tubular member and the distal portion of the outer tubular member; and

a medical balloon expandable between a first state and a second state, the medical balloon having a proximal end and a distal end, the proximal end of the medical balloon being engaged to the proximal rotatable member and the distal end of the medical balloon being engaged to the distal rotatable member.

17. The catheter assembly of claim 16 wherein the proximal portion of the outer tubular member and the inner tubular member define a space, the space defining an inflation lumen.

18. The catheter assembly of claim 17 wherein at least a portion of the outer tubular member underlying the medical balloon defines at least one inflation port, the at least one inflation port in fluid communication with the inflation lumen.

19. The catheter assembly of claim 16 wherein the distal rotatable member is disposed about the distal portion of the outer tubular member.

20. The catheter assembly of claim 19 wherein the distal portion of the outer tubular member is sealingly engaged to the distal portion of the inner tubular member.

21. The catheter assembly of claim 16 further comprising a proximal stop member and a distal stop member, the proximal stop member being fixedly engaged to the proximal portion of the outer tubular member, the distal stop member being fixedly engaged to at least one of the distal portion of the inner tubular member and the distal portion of the outer tubular member.

22. The catheter assembly of claim 21 wherein the proximal stop member is positioned proximally adjacent to the proximal rotatable member and the distal stop member is positioned distally adjacent to the distal rotatable member.

23. The catheter assembly of claim 22 wherein when the medical balloon is expanded from the first position to the second position the proximal rotatable member is moved longitudinally to engage the proximal stop member and distal rotatable member is moved distally to engage the distal stop member

24. The catheter assembly of claim 16 further comprising a secondary tubular member, the secondary tubular member being engaged to an external surface of the medical balloon.

25. The catheter assembly of claim 24 wherein the secondary tubular member has an open position and a closed position, in the closed position the secondary tubular member defining a substantially hollow interior open at both ends, the substantially hollow interior defining secondary lumen, the secondary lumen constructed and arranged to receive a secondary elongate guide member therethrough, in the open position the secondary tubular member defines a longitudinal opening that exposes the secondary lumen thereby releasing the secondary elongate guide member from the secondary tubular member.

26. The catheter assembly of claim 25 wherein the secondary tubular member is disposed about a secondary elongate guide member, the secondary tubular member being moveable relative to the secondary elongate guide member.

27. The catheter assembly of claim 26 further comprising a stent, the stent comprising a substantially hollow tubular member having a plurality of openings therethrough, the stent being disposed about at least a portion of the medical balloon when the stent is in the unexpanded position, the stent being expandable from the unexpanded position to an expanded position, the stent being in the unexpanded position when the balloon is in the first state, the stent being in the expanded position when the medical balloon is in the second state.

28. The catheter assembly of claim 27 wherein the stent is selected from the group consisting of a balloon expandable stent, a self-expanding stent and any combination thereof.

29. The catheter assembly of claim 26 wherein the secondary tubular member is positioned between at least a portion of the stent and the medical balloon.

30. The catheter assembly of claim 29 wherein the secondary elongate guide member exits the secondary tubular member and passes through one of the plurality of openings through the substantially hollow tubular member of the stent.

31. A method of placing a stent at a bifurcation comprising the steps of:

advancing a first guide wire through a body lumen to a first branch of a vessel bifurcation;

advancing a second guide wire through the body lumen to a second branch of the vessel bifurcation;

advancing a catheter assembly to the vessel bifurcation along the first guide wire and a second guide wire, the catheter assembly comprising:

a medical balloon disposed about the first guide wire, the medical balloon being freely rotatable about the first guide wire,

a tubular member engaged to an external surface of the medical balloon, the tubular member being disposed about the second guide wire, and

a stent, the stent being disposed about at least a portion of the medical balloon and the tubular member, the second guide wire passing through at least one opening defined by the stent.

32. A delivery assembly for precisely positioning a stent at a bifurcated passage, the assembly comprising:

a first guide wire adapted for receipt into a passage;

a side branch guide wire adapted for receipt into a side branch passage; and

a stent assembly carried by the first guide wire and operatively associated with the side branch guide wire, the assembly having proximal and distal ends, selectively rotatable relative to the first guide wire whereby the side branch guide wire is properly positioned in the side branch passage.

33. The delivery assembly of claim 32 further comprising an inner hollow member receiving the first guide wire therethrough.

34. The delivery assembly of claim 33 further comprising a balloon received on the inner hollow member for deploying the stent assembly.

35. The delivery assembly of claim 34 wherein the balloon rotates relative to the inner hollow member.

36. The delivery assembly of claim 34 wherein the inner hollow member has an opening that operatively communicates with an interior of the balloon.

37. The delivery assembly of claim 33 further comprising first and second fixed members disposed in axially spaced relation on the inner member.

38. The delivery assembly of claim 37 further comprising a balloon axially received between the fixed members.

39. The delivery assembly of claim 33 further comprising first and second rotatable members received on the inner hollow member, the rotatable members secured to first and second ends of a balloon to permit selective rotation of the balloon and passively orient the side branch guide wire in the side branch passage.

40. The delivery assembly of claim 39 wherein the inner hollow member forms a fluid passage that conveys fluid to the balloon.

41. The delivery assembly of claim 32 further comprising a carrier for the side branch

guide wire carried on the balloon.

42. The delivery assembly of claim 41 wherein the carrier includes a longitudinal slit that selectively opens in response to inflation of the balloon for releasing the side branch guide wire.

43. A method of delivering a stent to a stenosed bifurcated passage comprising the steps of:

inserting a main guide wire, balloon, and stent in a passage;

inserting a side branch guide wire at a side branch passage; and

allowing the stent to rotate relative to the main guide wire to properly orient same.

44. The delivery method of claim 43 comprising inflating a balloon to deploy the stent.

45. The delivery method of claim 44 further comprising releasing the side branch guide wire in response to inflating the balloon.

46. The assembly of claim 45 wherein the releasing step includes opening a side tube secured to the balloon to release the side branch guide wire.

47. A stent delivery assembly for a bifurcated passage comprising:

a first guide wire for receipt in a main branch of the bifurcated passage;

a second guide wire for receipt in a side branch of the bifurcated passage; and

a stent carried by the first guide wire and operatively associated with the second guide wire, the stent rotatably mounted relative to the first guide wire so that insertion of the second guide wire into the side branch properly orients the stent.

48. The assembly of claim 47 farther comprising a balloon rotatably received on the first guide wire.

49. The assembly of claim 49 further comprising first and second rotating

members received over the first guide wire and receiving corresponding first and second ends of the balloon to permit selective rotation of the balloon and passively orient the side branch guide wire via the side branch passage.

50. The assembly of claim 48 wherein the stent is self-expanding.

51. The assembly of claim 47 further comprising a balloon rotatably received on the fast guide wire for selectively expanding the stent and a side branch guide wire Carrier.

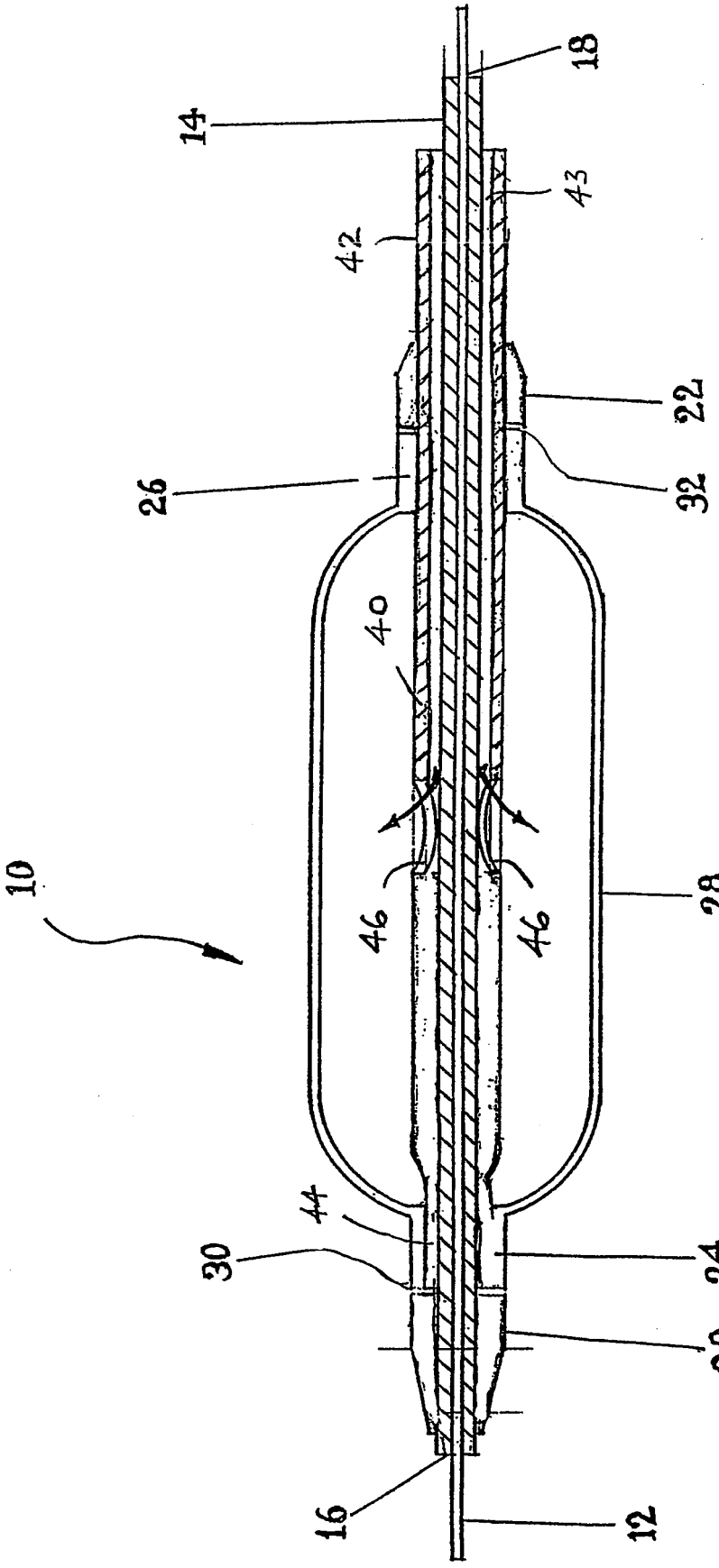

fig. 1

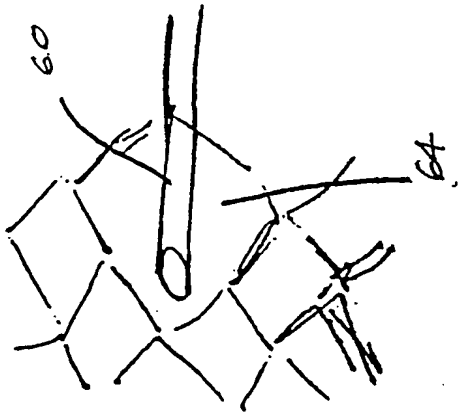

FIG. 5

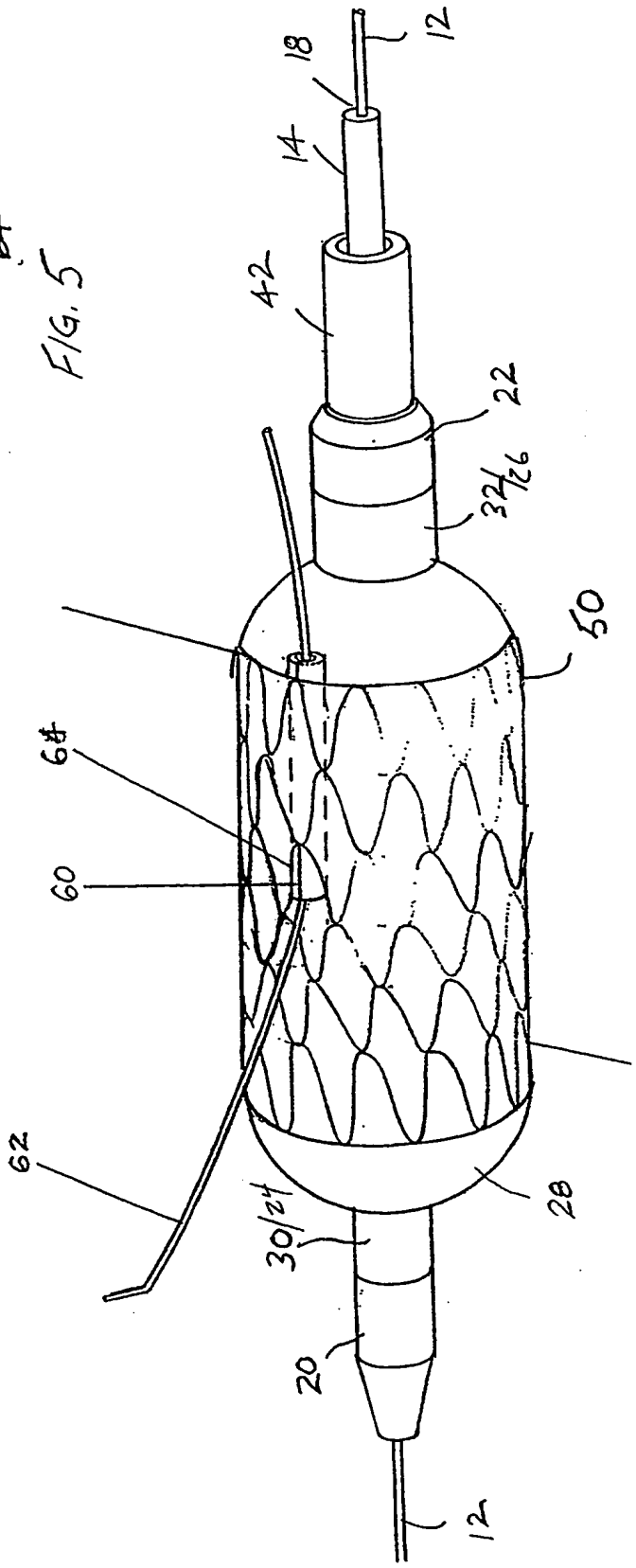

fig. 2

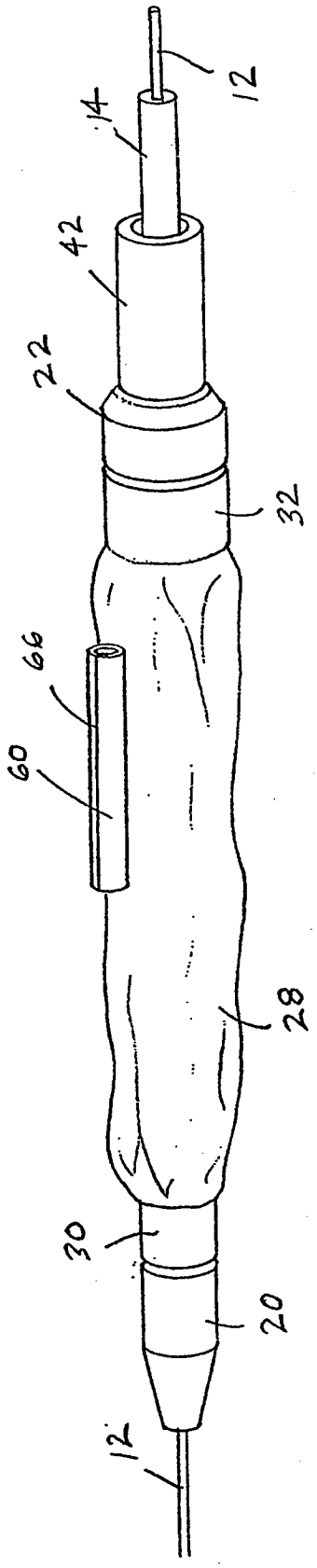

FIG. 3

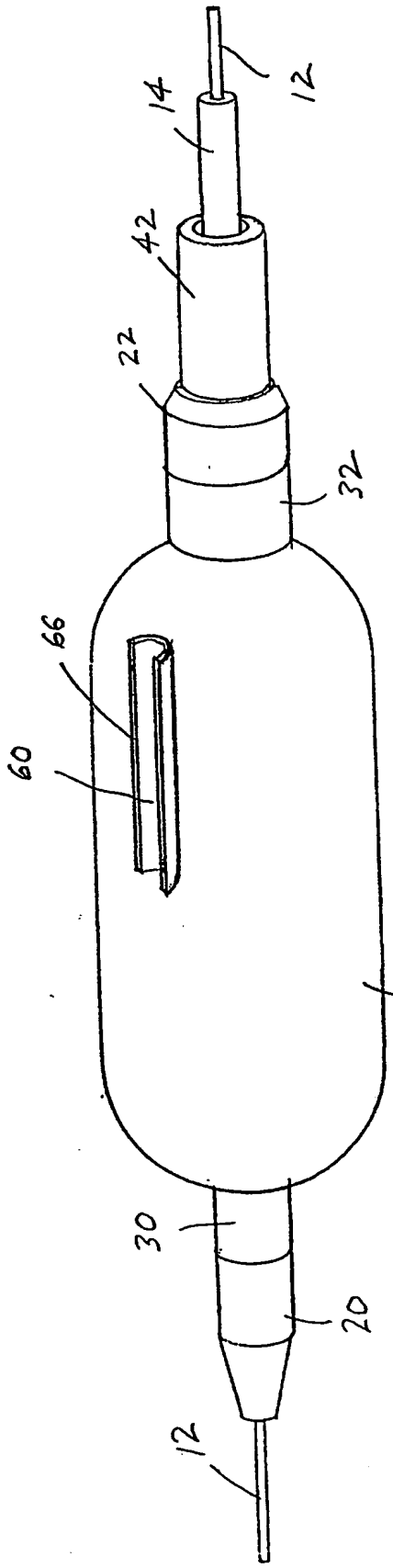

FIG. 4

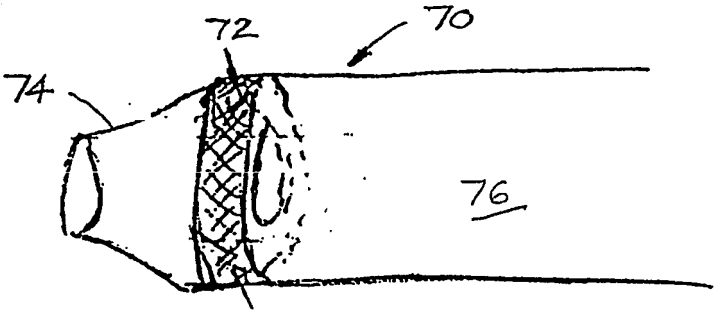

FIG. 6

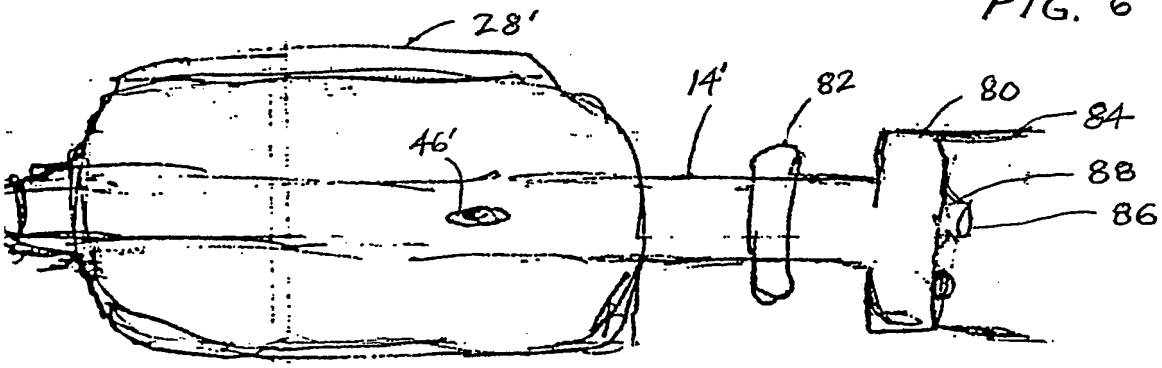

FIG. 7

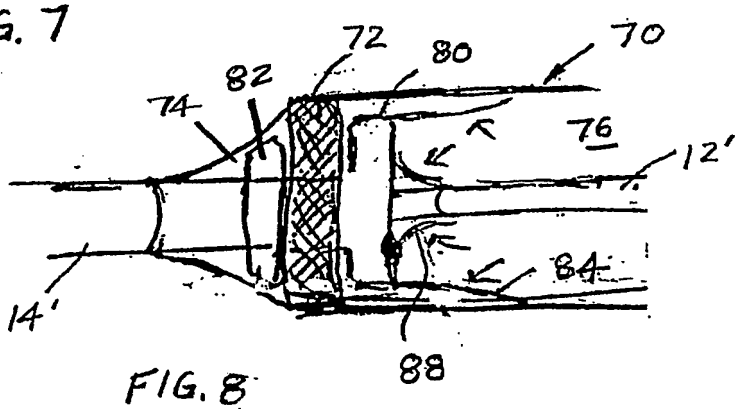

FIG. 8

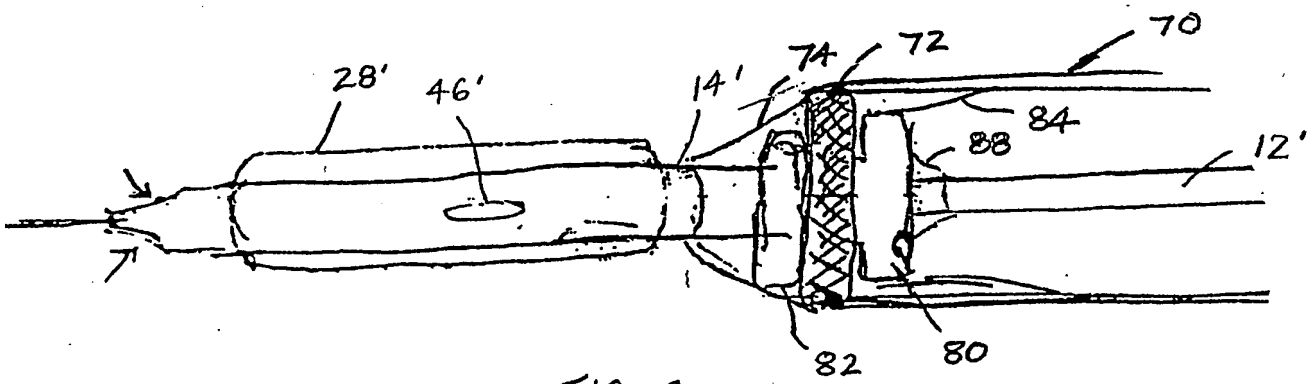

FIG. 9

INTERNATIONAL SEARCH REPORT

Int nal Application No
PCT/US 02/26736

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 221 090 B1 (WILSON W STAN) 24 April 2001 (2001-04-24)	32-34, 36,41, 47,48, 50,51
A	column 14, line 5 - line 42 column 15, line 31 - line 59 column 17, line 28 - line 32 figures 7A-13D	1,14,16, 35,37, 39,49

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 October 2002	08/11/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Amaro, H

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Ir ›nal Application No
PCT/US 02/26736

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
E	US 2002/072755 A1 (CHOI STEVEN B ET AL) 13 June 2002 (2002-06-13) page 1, paragraph 5	16-18,24
P,A	page 2, paragraph 23 -page 2, paragraph 27 page 3, line 13, paragraph 28 - line 18	1,14,32, 47

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-30

A catheter assembly comprising an elongate guide member, a tubular member, an expandable medical balloon and an outer tubular member that can be a proximal shaft member. The tubular member being rotatable in relation to the outer tubular member.

2. Claims: 32-42,47-51

A stent delivery assembly for precisely positioning a stent at a bifurcated passage comprising first and second guide wires and a stent.

INTERNATIONAL SEARCH REPORT

ational application No.
PCT/US 02/26736

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 31, 43-45
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [X] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Inte al Application No
PCT/US 02/26736

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6221090 B1	24-04-2001	US 6165195 A	26-12-2000
		DE 69806550 D1	22-08-2002
		EP 1199052 A2	24-04-2002
		EP 0897700 A1	24-02-1999
		JP 11057019 A	02-03-1999
		US 6264682 B1	24-07-2001
		US 6361544 B1	26-03-2002
		US 6221098 B1	24-04-2001
		US 2001029396 A1	11-10-2001
		US 2001037138 A1	01-11-2001
		US 2001037116 A1	01-11-2001
US 2002072755 A1	13-06-2002	NONE	

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

CORRECTED VERSION

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International Bureau

(43) International Publication Date
6 March 2003 (06.03.2003)

PCT

(10) International Publication Number
WO 03/017872 A1

(51) International Patent Classification[7]: A61F 2/06

(21) International Application Number: PCT/US02/26736

(22) International Filing Date: 22 August 2002 (22.08.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/314,467 23 August 2001 (23.08.2001) US

(71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US]; One Scimed Place, Maple Grove, MN 55311 (US).

(72) Inventor: GUMM, Darrell C.; 10114 North Laurel Wood Court, Peoria, IL 61615 (US).

(74) Agent: URZEDOWSKI, James M.; Vidas, Arrett & Steinkraus, P.A., Suite 2000, 6109 Blue Circle Drive, Minnetonka, MN 55343-9185 (US).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

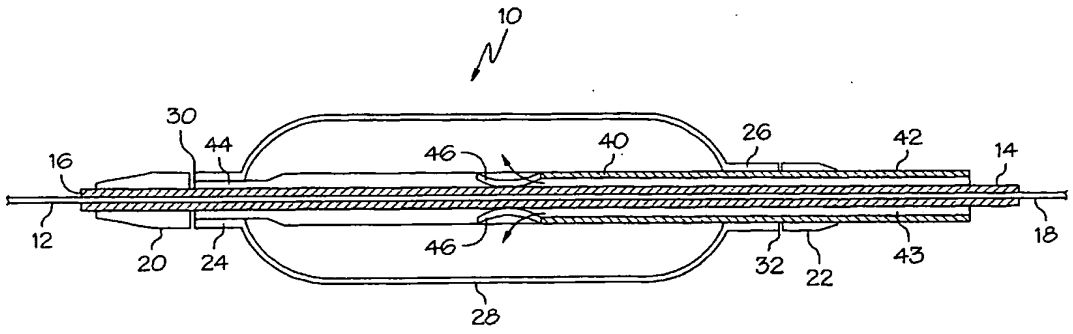
Published:
— with international search report

(48) Date of publication of this corrected version:
18 December 2003

(15) Information about Correction:
see PCT Gazette No. 51/2003 of 18 December 2003, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ROTATING STENT DELIVERY SYSTEM FOR SIDE BRANCH ACCESS AND PROTECTION AND METHOD OF USING SAME.



(57) Abstract: A catheter assembly and method of use comprises advancing a catheter having a rotatably mounted balloon (28,28') relative to the primary guide wire (12,12') to a vessel bifurcation along first and second guide wires (62).

WO 03/017872 A1

TITLE

Rotating Stent Delivery System for Side Branch Access and Protection and Method of Using Same

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority from US provisional application 60/314,467, filed August 23, 2001 the entire contents of which are incorporated herein by reference.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

Not Applicable

BACKGROUND OF THE INVENTION

Field of the Invention

At least one embodiment of the present invention is directed to the field of stents and stent delivery systems used to treat stenoses, and more particularly to stenoses at a bifurcation of a passage.

Description of the Related Art

Stent systems are widely used in the treatment of stenoses. Intravascular stents are used in coronary, renal, and carotid arteries, for example, to maintain an open passage through the artery. In patients whose coronary heart disease consists of focal lesions, stents have proven effective. For example, where only a single coronary artery is clogged or where there are short blockages in more than a single artery, stents have been used with a great amount of success. An intravascular stent may be positioned in a clogged artery by a catheter and is often set in place by inflating a balloon upon which the stent is mounted. This expands the diameter of the stent and opens the previously clogged artery. The balloon is then deflated and removed from the patient while the stent retains an open passage through the artery.

It is recognized, however, that a stent can be deployed in manners other than inflating and deflating a balloon. For example, self-expanding stents have been

developed in which a cover is removed from over a stent, thereby allowing the stent to deploy or spring into place. It is also contemplated that other deployment mechanisms or means may be used or developed to advantageously deliver and deploy a stent in position.

Nevertheless, a need still exists for properly delivering and locating a stent at a bifurcation. Although efforts have been made to use a stent at bifurcations, these sites have previously been inadequately treated by a stent. For example, U.S. Patent No. 5,749,825 is representative of a catheter system that treats stenoses at an arterial bifurcation. The disclosure of 5,749,825 is hereby incorporated by reference.

A stent having different diameters has been proposed to allow placement in both a main passage, such as an artery, and a side branch passage, such as a continuation branch artery. Additionally, these stents generally have a circular opening which allows for unimpeded blood flow into the side branch artery. However, problems are still encountered in orienting the stent relative to the side branch at the bifurcation of the main and branch passages.

Many current devices rely on either passive torque (e.g., pushing the stent forward and allowing the stent that is fixed on the guide wire/balloon to passively rotate itself into place) or creating torque from outside of the patient to properly orient the stent delivery system in the passage. These devices and methods of achieving proper angular orientation have not been shown to be effective in properly placing and positioning the stent. As will be appreciated and understood by those skilled in the art, improper placement of the stent with respect to its rotational or circumferential orientation, or its longitudinal placement, could lead to obstruction of the side branch passage. It is important to properly position or center an opening formed in the bifurcated stent with the side branch passage to maximize flow therethrough.

Thus, a need exists for effectively treating stenosed passage bifurcations. This need includes more precise and exact longitudinal placement and rotational/ circumferential orientation of the stent.

Commercially available devices do not maintain side branch access at the time of stent deployment. This results in the potential for plaque shift and occlusion of

the side branch passage.

It would also be advantageous if stents could be placed across the side branch while wire position is maintained thereby helping to protect and secure further access to the side branch.

All US patents and applications and all other published documents mentioned anywhere in this application are incorporated herein by reference in their entirety.

Without limiting the scope of the invention a brief summary of some of the claimed embodiments of the invention is set forth below. Additional details of the summarized embodiments of the invention and/or additional embodiments of the invention may be found in the Detailed Description of the Invention below.

A brief abstract of the technical disclosure in the specification is provided as well only for the purposes of complying with 37 C.F.R. 1.72. The abstract is not intended to be used for interpreting the scope of the claims.

BRIEF SUMMARY OF THE INVENTION

Some embodiments of the present invention include a freely rotating deployment system for a stent assembly maintaining side branch access and protection.

The present invention contemplates a new and improved apparatus and method that improves the orientation of a stent by providing a more exact placement of the stent relative to the side branch passage. This, in turn, leads to better protection of the side branch passage. The present invention has the potential for improvement in trackability of the stent delivery system.

At least one embodiment of the invention includes a freely rotatable catheter balloon surrounding a main hollow member or hypotube. The stent surrounds both the catheter balloon and the main hypotube. A side branch hollow member or side branch hypotube is attached to the catheter balloon and lies underneath the stent. A distal end of the side branch hypotube exits the stent at a desired longitudinal position while a proximal end of the side branch hypotube extends beyond the proximal end of the stent. At the distal exit point, the stent

includes an opening that, after deployment of the stent, allows for blood flow through the ostium of the side branch artery.

The balloon is connected to the stent delivery system. In some embodiments, the balloon is attached both distally and proximally to rotate freely about the main hypotube. The rotating members rotate about the main hypotube and are limited longitudinally by first and second fixed members non-rotatably secured to the *main* hypotube. The *balloon* stent assembly rotates freely about the axis defined by the main hypotube and any radial movement is limited by the main hypotube. This construction allows the side branch guide wire to direct the stent assembly to rotate freely and passively to the proper circumferential orientation. Upon inflating the balloon, the fixed and rotated members secure the circumferential orientation of the stent delivery system. Thus, the side branch guide wire properly orients the stent delivery system in its correct position relative to the side branch.

A primary feature of some embodiments is that at the time of positioning the stent, the stent will be properly oriented relative to the side branch, i.e., a stent delivery system and method that correctly positions the stent in a bifurcated passage.

Another advantageous feature is side branch protection with the guide wire during stent deployment.

Another benefit of this invention resides in proper alignment of the stent delivery system in a bifurcated passage to achieve correct circumferential orientation relative to a side branch passage, and securing the desired orientation.

Yet another benefit of this invention is the ability to properly place the stent delivery system longitudinally relative to the side branch.

A further advantage of the system is that tangled wires pose less of a problem.

These and other embodiments which characterize the invention are pointed out with particularity in the claims annexed hereto and forming a part hereof. However, for a better understanding of the invention, its advantages and objectives obtained by its use, reference should be made to the drawings which form a further part hereof and the accompanying descriptive matter, in which there is illustrated and described a embodiments of the invention.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

A detailed description of the invention is hereafter described with specific reference being made to the drawings.

FIG. 1 is a cross-sectional side view of a rotating stent delivery catheter assembly for stenting an arterial bifurcation in its pre-deployment configuration, with the catheter balloon shown inflated.

FIG. 2 is a perspective view of the stent delivery assembly of FIG. 1 shown with a stent disposed about the balloon.

FIG. 3 is a perspective view of the stent delivery catheter assembly of FIG. 1 as it would appear in the collapsed state prior to having a stent mounted on the balloon.

FIG. 4 is a perspective view of a stent delivery system with the balloon in an inflated state and the side branch hypotube in an open condition.

FIG. 5 is an enlarged view of the distal exit point of the side branch hypotube and the opening of the rotating stent delivery catheter assembly of FIG. 2.

FIG. 6 is a perspective view of a proximal shaft of an alternate stent delivery catheter assembly having only one rotating joint that is self sealing when pressure is applied or withdrawn.

FIG. 7 is an enlarged side view of a distal end of the rotating balloon assembly associated with FIG. 6.

FIG. 8 is an enlarged side view of the combined components of FIG. 6 and 7, specifically portions of the distal end of the proximal fixed shaft in FIG. 6 combined with the proximal end of the freely rotatable distal portion in FIG. 7 creating a rotating stent delivery catheter assembly with a single rotating joint that is self sealing.

FIG. 9 is an enlarged side elevational view of FIG. 6 and 7 showing the combined of components of FIGS. 6-8 in their entirety.

DETAILED DESCRIPTION OF THE INVENTION

While this invention may be embodied in many different forms, there are described in detail herein specific preferred embodiments of the invention. This description is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

For the purposes of this disclosure, like reference numerals in the figures shall refer to like features unless otherwise indicated.

Referring now to the drawings wherein the showings are for the purposes of illustrating the preferred embodiments of the invention only and not for purposes of limiting same, FIG. 1 shows a stent delivery system or assembly 10. Assembly 10 includes a first guide member, or main guide wire 12 that extends axially through a first hollow or tubular member 14. The first hollow member 14 will also be identified as a main hypotube, although it will be appreciated that the particular shape or configuration of this component may change from that illustrated in the drawings. The main guide wire 12 is used as the delivery guide of the stent catheter assembly 10 to a stenosed region of a passage such as an artery (not shown). The main hypotube 14 is preferably a hollow cylinder with openings on both its distal and proximal ends, respectively end 16 and end 18, which allows for passage of the main guide wire 12 therethrough. A first fixed member, or distal fixed body 20 and a second fixed member, or proximal fixed body 22 are non-rotatably secured to distal end 16 and proximal end 18 of the main hypotube 14. Although described as separate elements, it will be understood that the fixed bodies 20 and 22 and the main hypotube 14 can be separate components that are secured together or an integrally formed assembly if desired for ease of manufacture or assembly. The fixed bodies 20 and 22 are preferably tapered from smaller diameter, axially outer ends to larger diameter, intermediate ends for reasons that will become more apparent below.

A first rotating member or distal rotating member 24 and a second rotating member or proximal rotating member 26 are axially spaced apart and located between the distal fixed body 20 and proximal fixed body 22. The rotating members 24 and 26 are preferably of the same general diameter throughout their length and rotate freely about the axis of the main hypotube 14.

Sealed to the proximal and distal rotating members 24 and 26 are opposite ends of a catheter balloon 28. A distal end 30 of the catheter balloon is sealingly joined to (or

integrally formed with) the distal rotating member 24 while a proximal end 32 of the catheter balloon is sealingly joined to (or integrally formed with) the proximal rotating member 26. Thus, the balloon is free to rotate relative to the main hypotube, a feature that provides advantages and benefits over known stent assemblies. It is also contemplated that the rotating members 24 and 26 can be formed of sealing or elastomeric material (or incorporate a separate seal member) so that slight axial movement of the balloon 28 and of the rotating members 24 and 26 engages and seals against the fixed bodies 20 and 22 upon inflation of the balloon 28. The balloon 28 and the rotating members 24 and 26 can hold high pressure and seal at the ends. It will be appreciated that the rotating members 24 and 26 are preferably constructed to maintain a cylindrical configuration under pressure so that the balloon 28 is free to rotate relative to the main hypotube 14 when pressurized.

In some embodiments the stent delivery catheter system further includes an outer hollow/tubular member or outer hypotube 40 received over the main hypotube 14. The outer hypotube 40 is radially spaced from the main hypotube 14 at a first or proximal end 42 to define an annular space 43 through which fluid from an external source (not shown) is introduced to inflate the balloon. In at least one embodiment, a second or distal end 44 of the outer hypotube 40 is sealed to the main hypotube 14 so that fluid cannot escape therefrom. Alternatively, the distal end of the outer hypotube extends only partially into the balloon 28. In addition, one or more openings, or contrast ports, 46 are provided in the outer hypotube 40 at a location within the balloon 28 so that the fluid can enter the cavity defined between the balloon 28 and the outer hypotube 40 as illustrated by the directional arrows in FIG. 1. Alternatively, the opening 46 may define the distal end of the outer hypotube 40. In at least one embodiment, the balloon 28 is fully inflated at the proximal end 42 and then begins to inflate at the distal end 44. The outer hypotube 40 may be advantageously and integrally formed with the first and second fixed members 20 and 22 for ease of manufacture, although it will be appreciated that these may be separate members without departing from the scope and intent of the invention.

A conventional or specially designed medical device, such as a stent 50, encloses a portion of the catheter balloon 28, such as is shown in FIG. 2. The stent 50 is typically a metal sleeve of mesh construction that is advanced into the stenosis riding on the balloon 28 of the catheter assembly 10. Once properly positioned, the balloon 28 is inflated with an inflation

fluid, such as saline and contrast, through the passage 43 between the main hypotube 14 and the outer hypotube 40, which expands the balloon 28 and expands or radially opens the stent 50 to compress an atheroma that is narrowing the passage wall. Although the balloon 28 is subsequently deflated for removal from the patient with the catheter assembly 10, the stent 50 remains in its expanded state allowing increased flow through the previously closed/blocked (stenosed or narrowed) region. Alternatively, a self-expanding stent not requiring a balloon for delivery or deployment can be used without departing from the scope and intent of the present invention.

A second or branch tubular member 60, also referred to as a side branch hypotube, is provided between the catheter balloon 28 and the stent 50. As evident in FIG. 2, the side branch hypotube 60 carries or receives a side branch guide wire 62. The side branch hypotube 60 extends from the proximal end of the stent 50 between the stent and balloon and exits the stent at an intermediate longitudinal position through an opening 64. The opening 64 provides for both the exit of the side branch hypotube 60, as well as the unobstructed passage of blood flow into the side branch passage once the stent has been deployed. It should be understood, however, that the side branch hypotube opening 64 could be placed at any convenient position along the stent.

An enlarged view of the side branch hypotube opening 64 in the stent 50 is shown in FIG. 5. The side branch hypotube 60 exits from underneath the proximal end of the stent. Upon deployment of the stent 50, the side branch hypotube opening 64 allows for unobstructed blood flow to the ostium of the side branch passage. As will also be appreciated, the side branch hypotube 60 is fixed or secured to the exterior of the balloon. Thus, the side branch hypotube 60, balloon 28, and rotating members freely rotate as a unit relative to the main hypotube 14 for accurate, passive positioning with the side guide wire and thus accurate positioning of the stent 50 relative to a saddle point of the bifurcated passage. With continued reference to FIG. 2, the catheter balloon 28 is inflated, the stent 50 is deployed, and the rotating members 24 and 26 are interlocked with the fixed members 20 and 22 to stop the rotating action of the stent delivery system and create a pressure tight system.

The side branch hypotube 60 may also be slit 66 along its longitudinal length to facilitate removal of the side guide wire 62 as is shown in FIGs. 3 and 4. The side branch

hypotube 60 is secured to the balloon 28 along its length at a circumferential location opposite the longitudinal slit, i.e., diametrically opposite the slit 66. The natural elasticity of the side branch hypotube 60 is utilized so that when the balloon 28 is inflated, such as is shown, the side branch hypotube 60 is substantially cylindrical in shape to enclose the portion of the side guide wire 62 therein such as is shown in FIG. 2. When the balloon is inflated, it exerts a tensile force on the side branch hypotube 60 that opens the hypotube 60 along its length, such as in the manner shown in FIG. 4. As a result the side guide wire 62 is released through the slit 66. When the balloon 28 is deflated, such as is shown in FIG. 3, the side branch hypotube 60 again adopts a cylindrical conformation whereby the remainder of the stent delivery system (balloon and catheter) can be easily removed.

The split side branch hypotube 60 offers another desirable feature. The split hypotube 60 allows for immediate placement of a second balloon into the side branch for simultaneous "kissing" balloon inflation. In other words, first and second balloons are simultaneously located in the main and side branch passages such that their proximal ends abut and their distal ends are placed in each respective branch. This is to be contrasted with use of an unsplit or solid side branch hypotube which would require removal of the first balloon prior to insertion of a balloon in the side branch.

An alternative rotating stent delivery system is illustrated in FIGs. 6-9. For purposes of brevity, like components will be referenced by like numerals with a primed suffix (') and new elements will be identified by new numerals.

A proximal shaft is generally well known in the art and may take numerous forms; however, the proximal shaft 70 shown in FIGs. 6-9 preferably includes a bushing 72 at a distal end and a seal 74 comprised of a soft material. The seal 74 is connected to the proximal shaft 70 and, as shown, tapers to a smaller diameter and envelops the main hypotube 14', as is shown in FIGs. 8 and 9. Within lumen 76 of the proximal shaft 70, the bushing 72 abuts against an interior distal end of the proximal shaft.

With reference now to FIG. 7, a distal rotating portion of proximal shaft 70 is shown. A separate hypotube 14' includes a proximal end with a first bushing 80 and a second bushing 82 axially spaced therefrom along the separate hypotube 14'. A second seal 84 comprised of a soft material, is connected to the first bushing 80 at the proximal end of the

separate hypotube 14'. The annular second seal 84 protrudes substantially parallel along the longitudinal axis of the main hypotube and extends axially beyond an opening 86 for the main branch guide wire (not shown). Additionally, a third annular seal 88 is shown connected to the first bushing 80. The third seal 88 has a smaller diameter and lies axially and radially inward of the second seal 84. The third seal 88 is also secured to the first bushing 80 of the separate hypotube 14' and tapers radially inward as it extends longitudinally in a direction away from the separate hypotube 14', to envelope the main guide wire 12'.

The integration of the proximal end of the separate hypotube 14' and the distal end of the proximal shaft 70 is shown in FIG. 8. Particularly, the first and second bushings 80, 82 of the hypotube 14' are of a diameter that allows them to fit under or within the particular components of the proximal shaft 70. Specifically, the second bushing 82 of the hypotube 14' is distal to the proximal shaft bushing 72 and is enveloped by the first soft seal 74 of the proximal shaft 70. The first bushing 80 of the hypotube 14' is adjacent to the bushing 72 of the proximal shaft and is enveloped by the proximal shaft 70.

With continued reference to FIG. 8, the integrated hypotube 14' and proximal shaft 70 are shown in a freely rotatable position. In this mode, the hypotube 14' rotates freely while the proximal shaft 70 remains fixed. Positive pressure allows the seals 82 and 88 extending from the first bushing 80 of the hypotube 14', to contact the proximal fixed shaft 70 and main guide wire 12' hence sealing the balloon delivery system 10' allowing for all positive pressure to be transferred to the balloon 28'. This provides for expansion of the balloon 28' and deployment of a stent such as previously described. Alternatively, as is shown in FIG. 9 negative pressure applied within the shaft 70 will create contact between the separate hypotube and the seal 74 of the proximal shaft 70. Also, contact will be created at the distal end of the separate hypotube between the soft material and the wire 12' creating a seal there as well. These seals allow for all negative pressure to be transmitted to the balloon allowing for collapse and then removal of the balloon.

Thus, it is apparent that a truly unique feature of the invention is a freely rotating stent assembly that provides a more exact placement of the stent relative to the side branch passage.

The invention has been described with reference to the preferred

embodiments. Obviously, modifications and alterations will occur to others upon a reading and understanding of this specification. For example, the illustrated embodiments use a balloon to expand the stent although, as briefly noted above, a self expanding or self deploying stent can be used without departing from the features of the present invention. Likewise, using a fixed wire on the distal end of the apparatus is also recognized as being consistent with the features of the present invention. Moreover, the preferred embodiments describe a side branch hypotube, either split or unsplit, that is associated with the side branch guide wire. It will be further appreciated that the side branch guide wire could be carried and/or released in a variety of other ways. The invention is intended to include all such modifications and alterations thereof.

The above disclosure is intended to be illustrative and not exhaustive. This description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the claims where the term "comprising" means "including, but not limited to". Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims.

Further, the particular features presented in the dependent claims can be combined with each other in other manners within the scope of the invention such that the invention should be recognized as also specifically directed to other embodiments having any other possible combination of the features of the dependent claims. For instance, for purposes of claim publication, any dependent claim which follows should be taken as alternatively written in a multiple dependent form from all prior claims which possess all antecedents referenced in such dependent claim if such multiple dependent format is an accepted format within the jurisdiction (e.g. each claim depending directly from claim 1 should be alternatively taken as depending from all previous claims). In jurisdictions where multiple dependent claim formats are restricted, the following dependent claims should each be also taken as alternatively written in each singly dependent claim format which creates a dependency from a prior antecedent-possessing claim other than the specific claim listed in such dependent claim below.

This completes the description of the preferred and alternate embodiments of the invention. Those skilled in the art may recognize other equivalents to the specific embodiment described herein which equivalents are intended to be encompassed by the claims attached hereto.

CLAIMS:

1. A catheter assembly comprising:

an elongate guide member, the elongate guide member extending from a proximal end to a distal end of the catheter assembly;

a tubular member disposed about a portion of the elongate guide member, the tubular member rotatable about the elongate guide member;

an expandable medical balloon having a proximal end and a distal end, the medical balloon disposed about at least a portion of the tubular member, the proximal end and the distal end of the medical balloon fixedly engaged to the tubular member; and

a proximal shaft member, the proximal shaft member disposed about a portion of the elongate guide member, the proximal shaft member having a distal end region, the distal end region being disposed about a proximal end region of the tubular member, the tubular member passively rotatable relative to the proximal shaft.

2. The catheter assembly of claim 1 wherein the tubular member defines an inflation port, the inflation port constructed and arranged to transmit an inflation media to and from the medical balloon from and to the proximal end of the catheter assembly.

3. The catheter assembly of claim 1 wherein the distal end region of the proximal shaft member is sealingly engaged to the proximal end region of the tubular member.

4. The catheter assembly of claim 1 wherein the proximal end region of the tubular member comprises a first bushing and the distal end region of the proximal shaft member comprises a second bushing, the first bushing engaged to the second bushing to form a fluid tight seal between the proximal end region of the tubular member and the distal end region of the proximal shaft member.

5. The catheter assembly of claim 4 wherein the proximal end region of the tubular member further comprises a third bushing, the second bushing positioned between the first bushing and the second bushing.

6. The catheter assembly of claim 3 further comprising a first annular seal, the first annular seal extending from the distal end region of the proximal shaft member to the proximal end region of the tubular member.

7. The catheter assembly of claim 6 wherein the first annular seal tapers from a first end engaged to the distal end region of the proximal shaft member to a narrower second end engaged to the tubular member.

8. The catheter assembly of claim 7 further comprising a second annular seal, the second annular seal extending from the distal end region of the proximal shaft member to the proximal end region of the tubular member, the second annular seal being positioned proximal to the first annular seal.

9. The catheter assembly of claim 8 further comprising a third annular seal, the third annular seal extending from the proximal end region of the tubular member to the elongate guide member.

10. The catheter assembly of claim 9 wherein the third annular seal tapers from a first end engaged to the proximal end region of the tubular member to a narrower second end engaged to the elongate guide member.

11. The catheter assembly of claim 1 wherein a proximal end region of the tubular member is sealingly engaged to the elongate guide member.

12. The catheter assembly of claim 11 further comprising a third annular seal, the third annular seal extending from the proximal end region of the tubular member to the elongate guide member.

13. The catheter assembly of claim 1 further comprising an expandable and implantable medical device, the expandable and implantable medical device being removably disposed about at least a portion of the medical balloon.

14. A catheter assembly comprising:

an elongate guide member, the elongate guide member extending from a proximal end to a distal end of the catheter assembly;

a tubular member disposed about a portion the elongate guide member, the tubular member rotatable about the elongate guide member;

a medical balloon having a proximal end and a distal end, the medical balloon disposed about at least a portion of the tubular member, the proximal end and the distal end of the medical balloon fixedly engaged to the tubular member; and

a proximal shaft member, the proximal shaft member disposed about a portion of the elongate guide member, the proximal shaft member having a distal end region, the distal end region of the proximal shaft member being disposed about a proximal end region of the tubular member, the distal end region of the proximal shaft member and the proximal end region of the tubular member forming a fluid tight seal therebetween, the tubular member being passively rotatable relative to the proximal shaft member.

15. The catheter assembly of claim 14 further comprising a stent, the stent being disposed about at least a portion of the medical balloon, the stent being expanded from a reduced state to an expanded state when the medical balloon is expanded.

16. A catheter assembly comprising:

an elongate guide member, the elongate guide member extending from a proximal end to a distal end of the catheter assembly;

an inner tubular member, the inner tubular member disposed about a portion of the elongate guide member;

an outer tubular member, the outer tubular member disposed about at least a portion of the inner tubular member;

a proximal rotatable member and a distal rotatable member, the proximal rotatable member being disposed about a proximal portion of the outer tubular member, the distal rotatable member being disposed about at least one of the distal portion of the inner tubular member and the distal portion of the outer tubular member, the proximal rotatable member forming a slidable and rotatable fluid seal with the proximal portion of the outer tubular member and the distal rotating member forming a slidable and rotatable fluid seal with the at least one of the distal portion of the inner tubular member and the distal portion of the outer tubular member; and

a medical balloon expandable between a first state and a second state, the medical balloon having a proximal end and a distal end, the proximal end of the medical balloon being engaged to the proximal rotatable member and the distal end of the medical balloon being engaged to the distal rotatable member.

17. The catheter assembly of claim 16 wherein the proximal portion of the outer tubular member and the inner tubular member define a space, the space defining an inflation lumen.

18. The catheter assembly of claim 17 wherein at least a portion of the outer tubular member underlying the medical balloon defines at least one inflation port, the at least one inflation port in fluid communication with the inflation lumen.

19. The catheter assembly of claim 16 wherein the distal rotatable member is disposed about the distal portion of the outer tubular member.

20. The catheter assembly of claim 19 wherein the distal portion of the outer tubular member is sealingly engaged to the distal portion of the inner tubular member.

21. The catheter assembly of claim 16 further comprising a proximal stop member and a distal stop member, the proximal stop member being fixedly engaged to the proximal portion of the outer tubular member, the distal stop member being fixedly engaged to at least one of the distal portion of the inner tubular member and the distal portion of the outer tubular member.

22. The catheter assembly of claim 21 wherein the proximal stop member is positioned proximally adjacent to the proximal rotatable member and the distal stop member is positioned distally adjacent to the distal rotatable member.

23. The catheter assembly of claim 22 wherein when the medical balloon is expanded from the first position to the second position the proximal rotatable member is moved longitudinally to engage the proximal stop member and distal rotatable member is moved distally to engage the distal stop member

24. The catheter assembly of claim 16 further comprising a secondary tubular member, the secondary tubular member being engaged to an external surface of the medical balloon.

25. The catheter assembly of claim 24 wherein the secondary tubular member has an open position and a closed position, in the closed position the secondary tubular member defining a substantially hollow interior open at both ends, the substantially hollow interior defining secondary lumen, the secondary lumen constructed and arranged to receive a secondary elongate guide member therethrough, in the open position the secondary tubular member defines a longitudinal opening that exposes the secondary lumen thereby releasing the secondary elongate guide member from the secondary tubular member.

26. The catheter assembly of claim 25 wherein the secondary tubular member is disposed about a secondary elongate guide member, the secondary tubular member being moveable relative to the secondary elongate guide member.

27. The catheter assembly of claim 26 further comprising a stent, the stent comprising a substantially hollow tubular member having a plurality of openings therethrough, the stent being disposed about at least a portion of the medical balloon when the stent is in the unexpanded position, the stent being expandable from the unexpanded position to an expanded position, the stent being in the unexpanded position when the balloon is in the first state, the stent being in the expanded position when the medical balloon is in the second state.

28. The catheter assembly of claim 27 wherein the stent is selected from the group consisting of a balloon expandable stent, a self-expanding stent and any combination thereof.

29. The catheter assembly of claim 26 wherein the secondary tubular member is positioned between at least a portion of the stent and the medical balloon.

30. The catheter assembly of claim 29 wherein the secondary elongate guide member exits the secondary tubular member and passes through one of the plurality of openings through the substantially hollow tubular member of the stent.

31. A method of placing a stent at a bifurcation comprising the steps of:

advancing a first guide wire through a body lumen to a first branch of a vessel bifurcation;

advancing a second guide wire through the body lumen to a second branch of the vessel bifurcation;

advancing a catheter assembly to the vessel bifurcation along the first guide wire and a second guide wire, the catheter assembly comprising:

a medical balloon disposed about the first guide wire, the medical balloon being freely rotatable about the first guide wire,

a tubular member engaged to an external surface of the medical balloon, the tubular member being disposed about the second guide wire, and

a stent, the stent being disposed about at least a portion of the medical balloon and the tubular member, the second guide wire passing through at least one opening defined by the stent.

32. A delivery assembly for precisely positioning a stent at a bifurcated passage, the assembly comprising:

a first guide wire adapted for receipt into a passage;

a side branch guide wire adapted for receipt into a side branch passage; and

a stent assembly carried by the first guide wire and operatively associated with the side branch guide wire, the assembly having proximal and distal ends, selectively rotatable relative to the first guide wire whereby the side branch guide wire is properly positioned in the side branch passage.

33. The delivery assembly of claim 32 further comprising an inner hollow member receiving the first guide wire therethrough.

34. The delivery assembly of claim 33 further comprising a balloon received on the inner hollow member for deploying the stent assembly.

35. The delivery assembly of claim 34 wherein the balloon rotates relative to the inner hollow member.

36. The delivery assembly of claim 34 wherein the inner hollow member has an opening that operatively communicates with an interior of the balloon.

37. The delivery assembly of claim 33 further comprising first and second fixed members disposed in axially spaced relation on the inner member.

38. The delivery assembly of claim 37 further comprising a balloon axially received between the fixed members.

39. The delivery assembly of claim 33 further comprising first and second rotatable members received on the inner hollow member, the rotatable members secured to first and second ends of a balloon to permit selective rotation of the balloon and passively orient the side branch guide wire in the side branch passage.

40. The delivery assembly of claim 39 wherein the inner hollow member forms a fluid passage that conveys fluid to the balloon.

41. The delivery assembly of claim 32 further comprising a carrier for the side branch

guide wire carried on the balloon.

42. The delivery assembly of claim 41 wherein the carrier includes a longitudinal slit that selectively opens in response to inflation of the balloon for releasing the side branch guide wire.

43. A method of delivering a stent to a stenosed bifurcated passage comprising the steps of:

inserting a main guide wire, balloon, and stent in a passage;

inserting a side branch guide wire at a side branch passage; and

allowing the stent to rotate relative to the main guide wire to properly orient same.

44. The delivery method of claim 43 comprising inflating a balloon to deploy the stent.

45. The delivery method of claim 44 further comprising releasing the side branch guide wire in response to inflating the balloon.

46. The assembly of claim 45 wherein the releasing step includes opening a side tube secured to the balloon to release the side branch guide wire.

47. A stent delivery assembly for a bifurcated passage comprising:

a first guide wire for receipt in a main branch of the bifurcated passage;

a second guide wire for receipt in a side branch of the bifurcated passage; and

a stent carried by the first guide wire and operatively associated with the second guide wire, the stent rotatably mounted relative to the first guide wire so that insertion of the second guide wire into the side branch properly orients the stent.

48. The assembly of claim 47 farther comprising a balloon rotatably received on the first guide wire.

49. The assembly of claim 49 further comprising first and second rotating

members received over the first guide wire and receiving corresponding first and second ends of the balloon to permit selective rotation of the balloon and passively orient the side branch guide wire via the side branch passage.

50. The assembly of claim 48 wherein the stent is self-expanding.

51. The assembly of claim 47 further comprising a balloon rotatably received on the fast guide wire for selectively expanding the stent and a side branch guide wire Carrier.

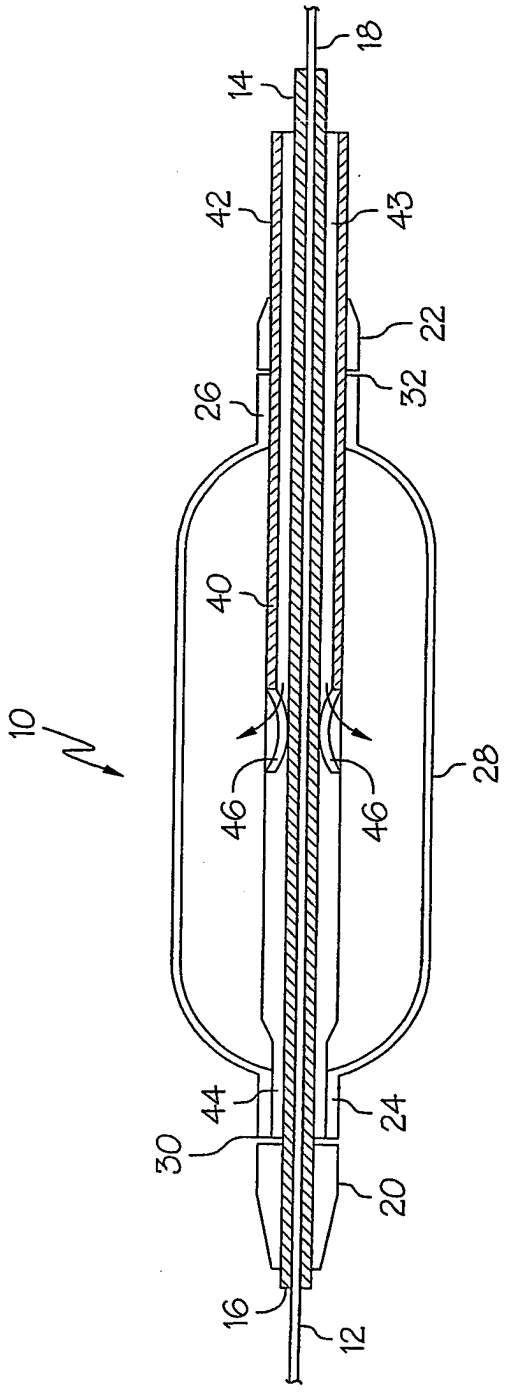


FIG. 1

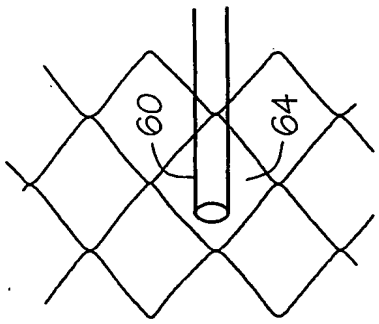


FIG. 5

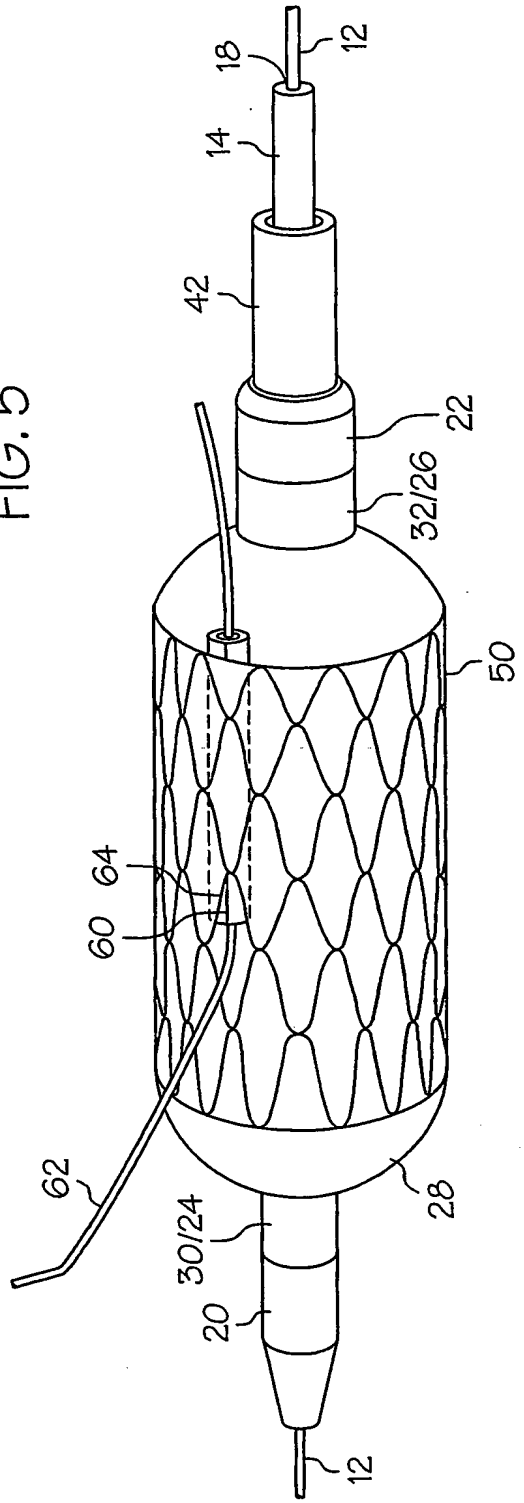


FIG. 2

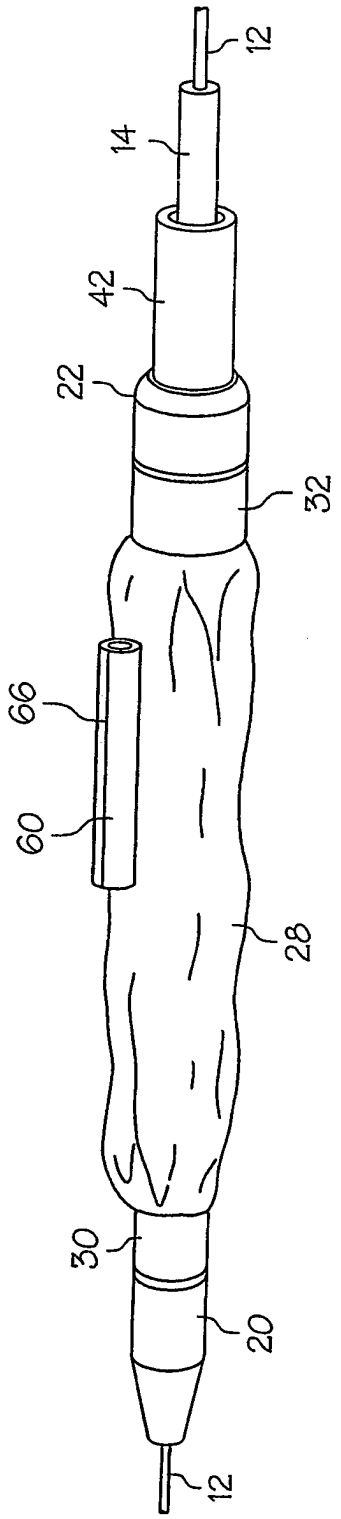


FIG. 3

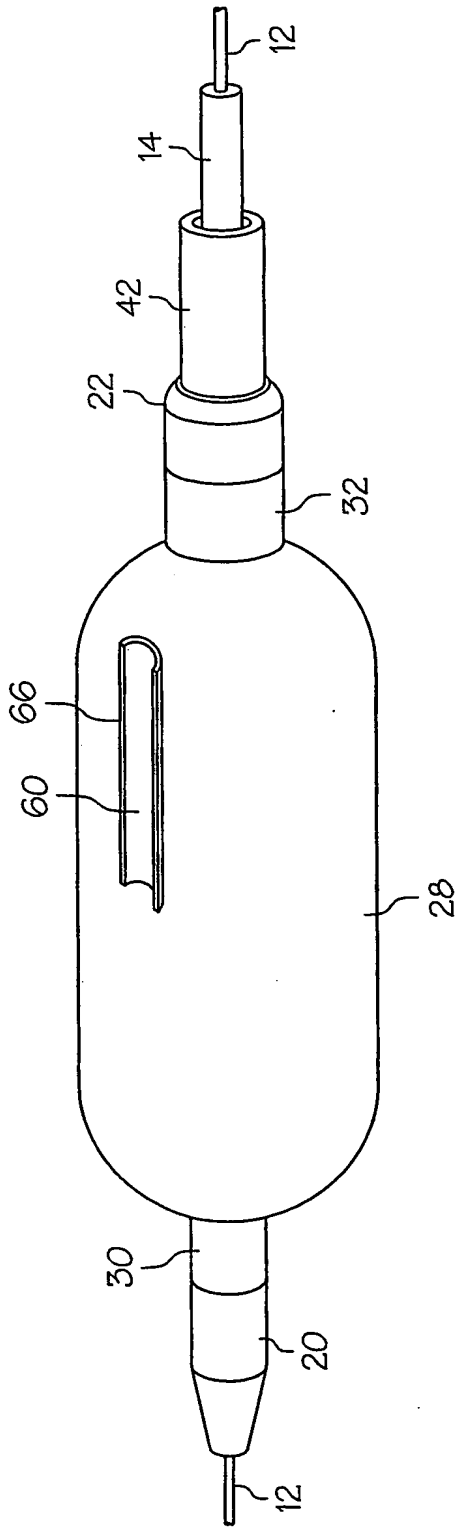


FIG. 4

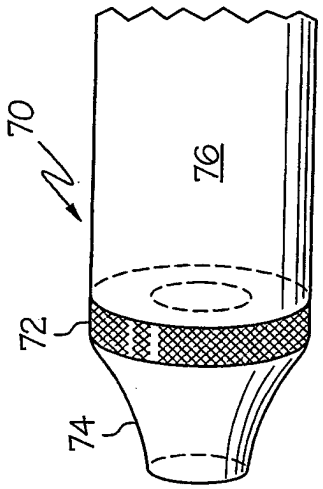


FIG. 6

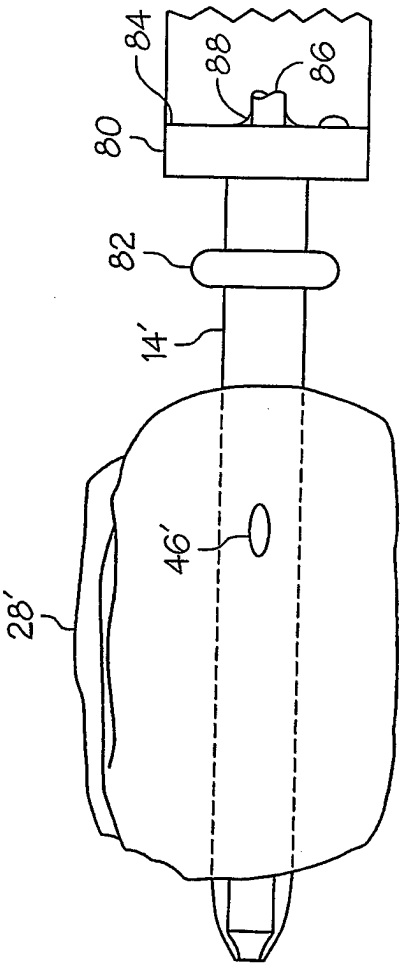


FIG. 7

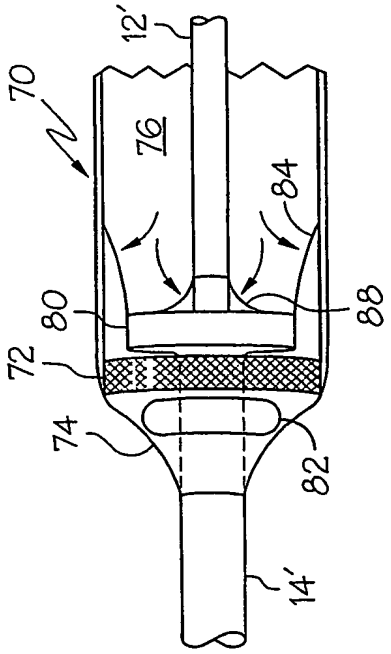


FIG. 8

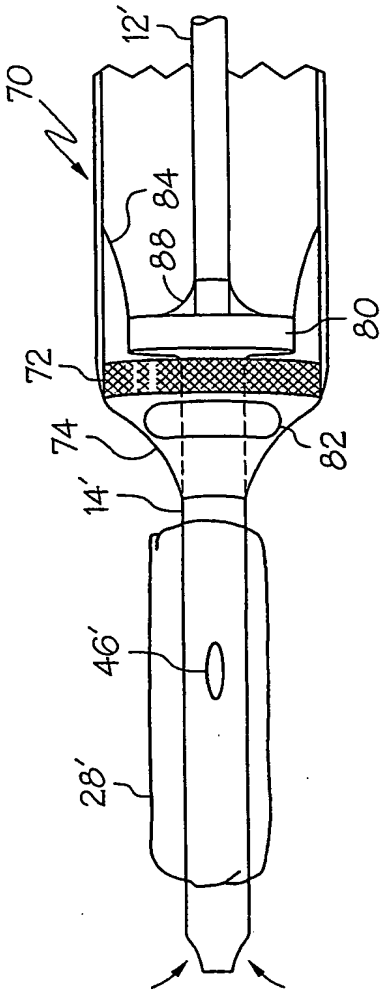


FIG. 9

INTERNATIONAL SEARCH REPORT

Intel ›nal Application No
PCT/US 02/26736

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 221 090 B1 (WILSON W STAN) 24 April 2001 (2001-04-24)	32-34, 36,41, 47,48, 50,51
A	column 14, line 5 - line 42 column 15, line 31 - line 59 column 17, line 28 - line 32 figures 7A-13D	1,14,16, 35,37, 39,49

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 October 2002	08/11/2002
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Amaro, H

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inte ınal Application No
PCT/US 02/26736

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
E	US 2002/072755 A1 (CHOI STEVEN B ET AL) 13 June 2002 (2002-06-13) page 1, paragraph 5	16-18,24
P,A	page 2, paragraph 23 -page 2, paragraph 27 page 3, line 13, paragraph 28 - line 18	1,14,32, 47

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-30

A catheter assembly comprising an elongate guide member, a tubular member, an expandable medical balloon and an outer tubular member that can be a proximal shaft member. The tubular member being rotatable in relation to the outer tubular member.

2. Claims: 32-42,47-51

A stent delivery assembly for precisely positioning a stent at a bifurcated passage comprising first and second guide wires and a stent.

INTERNATIONAL SEARCH REPORT

national application No.
PCT/US 02/26736

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 31,43-45
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [X] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 02/26736

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US 2002072755 A1	13-06-2002	NONE	